



10/813721

*CFJ*

Attorney Docket No. 00027.05CON

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of: Joshua D. Rabinowitz, et al. )

)

Patent No.: 7,022,312 ) Examiner: M. Haghigian

)

Issue Date: April 4, 2006 ) Group Art Unit: 1616

)

For: DELIVERY OF ANTIEMETICS )  
THROUGH AN INHALATION ROUTE )

**Certificate**

APR 24 2006

**of Correction**

Attn: Certificate of Correction Branch  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**REQUEST FOR CERTIFICATE OF CORRECTION OF PATENT  
FOR PTO MISTAKE (37 CFR 1.322(a))**

1. Attached is Form PTO/SB/44, which is suitable for printing.
2. The exact location where the error occurred is in the Claims, column 14, line 55, as follows:

Claim 9 reads:

9. The condensation aerosol according to Claim 8, wherein the condensation aerosol is characterized by an MMAD of 0.2 to 3 microns.

Claim 9 should read:

9. The condensation aerosol according to Claim 1, wherein the condensation aerosol is characterized by an MMAD of about 0.2 to about 3 microns.

3. These changes were submitted in an Amendment Under 37 C.F.R. § 1.312(a) filed on January 18, 2006. A copy of this Amendment together with a copy of the date-stamped postcard receipt is enclosed. The minor errors, described above, were incurred through the fault of the Office and therefore no fee is believed due.

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37 CFR 1.8

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to:  
Assistant Commissioner for Patents, Washington, D.C. 20231 on April 17, 2006.

Signature: Veronica Doucet  
Name: Veronica Doucet

*APR 24 2006*

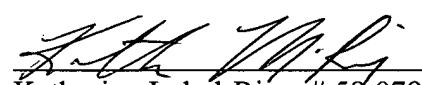
Entry of this Certificate of Correction is respectfully requested.

Please send the Certificate to:

Swanson & Bratschun, L.L.C.  
1745 Shea Center Drive, Suite 330  
Highlands Ranch, Colorado 80129

This constitutes authorization to charge all fees therefor to deposit account No. 19-5117, if not otherwise specifically requested. The undersigned hereby authorizes the charge of any fees created by the filing of this document or any deficiency of fees submitted herewith to deposit account No. 19-5117.

Respectfully submitted,

 4/17/06  
Katherine Lobel-Rice, # 58,079  
Swanson & Bratschun, L.L.C.  
1745 Shea Center Drive, Suite 330  
Highlands Ranch, Colorado 80129  
(303) 268-0066

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**UNITED STATES PATENT AND TRADEMARK OFFICE  
CERTIFICATE OF CORRECTION**

PATENT NO. : 7,022,312

DATED : 4/4/2006

INVENTOR(S) : Joshua Rabinowitz, Alejandro Zaffaroni

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Claim 21 (renumbered as Claim 9). The condensation aerosol according to Claim 1, wherein the condensation aerosol is characterized by an MMAD of about 0.2 to about 3 microns.

MAILING ADDRESS OF SENDER: Customer No. 28,571  
Swanson & Bratschun, LLC  
1745 Shea Center Drive, Suite  
330

PATENT NO.

7,022,312

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This collection of information is required by 37 CFR 1.322, 1.323, and 1.324. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1.0 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Attention Certificate of Corrections Branch, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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APR 24 2006

**DATE:** January 18, 2006

**APPLICANT:** Rabinowitz et al.

**APP NO:** 10813721

**RECEIPT IS HEREBY ACKNOWLEDGED OF:**

Part B Fees Transmittal: 1 pg

Amendment Under 37 CFR 1.312(a): 7 pgs

Check in the amount of \$1,000.00



Docket No.

00027.05CON

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Receipt.doc

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**PART B - FEE(S) TRANSMITTAL**

Complete and send this form, together with applicable fee(s), to: **Mail**

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CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

37485 7590 10/18/2005

SWANSON & BRATSCHUN, L.L.C.  
1745 SHEA CENTER DRIVE, SUITE 330  
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Tasha L. Pierce	(Depositor's name)
	(Signature)
January 18, 2006	(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,721	03/31/2004	Joshua D. Rabinowitz	00027.05CON	7409

TITLE OF INVENTION: DELIVERY OF ANTIEMETICS THROUGH AN INHALATION ROUTE

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$700	\$300	\$1000	01/18/2006
EXAMINER		ART UNIT	CLASS-SUB CLASS		
HAGHIGHATIAN, MINA		1616	424-045000		

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).  
 Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.  
 "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.

2. For printing on the patent front page, list  
(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,  
(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 Swanson & Bratschun, LLC  
2 William L. Leschensky  
3 \_\_\_\_\_

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

Alexza Pharmaceuticals, Inc.

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Palo Alto, California

Please check the appropriate assignee category or categories (will not be printed on the patent):  Individual  Corporation or other private group entity  Government

4a. The following fee(s) are enclosed:

- Issue Fee  
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4b. Payment of Fee(s):

- A check in the amount of the fee(s) is enclosed.  
 Payment by credit card. Form PTO-2038 is attached.  
 The Director is hereby authorized to charge the required fee(s), or credit any overpayment, to Deposit Account Number 19-5117 (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.  b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

The Director of the USPTO is requested to apply the Issue Fee and Publication Fee (if any) or to re-apply any previously paid issue fee to the application identified above. NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature Katherine L. Rice

Date January 18, 2006

Typed or printed name Katherine L. Rice

Registration No. 58,079

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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DATE OF NOTICE OF ALLOWANCE: October 18, 2005  
Attorney Docket: 00027.05CON

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of: Joshua D. Rabinowitz, et al. ) Examiner: M. Haghigian  
Serial No.: 10/813,721 ) Group Art Unit: 1616  
Filing Date: March 31, 2004 ) Confirmation No.: 7409  
For: DELIVERY OF ANTIEMETICS )  
THROUGH AN INHALATION ROUTE )

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**SUPPLEMENTAL AMENDMENT UNDER 37 C.F.R. § 1.312(a)**

Sir:

## AMENDMENT

Please amend the above-identified application as follows:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks begin on page 7 of this paper.

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**37 CFR 1.8**  
**CERTIFICATE OF MAILING**

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

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Signature: Leslie L. Pierce  
Name: Leslie L. Pierce

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Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (currently amended) A condensation aerosol for delivery of a drug selected from the group consisting of dolasetron, granisetron and metoclopramide,

wherein the condensation aerosol is formed by heating a thin layer containing the drug, on a solid support, to produce a vapor of the drug, and condensing the vapor to form a condensation aerosol; characterized by less than 10% drug degradation products by weight, and an MMAD of less than 5 microns.

2. (previously amended) The condensation aerosol according to Claim 1, wherein the condensation aerosol is formed at a rate greater than  $10^9$  particles per second.

3. (previously amended) The condensation aerosol according to Claim 2, wherein the condensation aerosol is formed at a rate greater than  $10^{10}$  particles per second.

4.-9. (cancelled)

10. (previously amended) A method of producing a drug selected from the group consisting of dolasetron, granisetron and metoclopramide in an aerosol form comprising:

a. heating a thin layer containing the drug, on a solid support, to produce a vapor of the drug, and  
b. providing an air flow through the vapor to form a condensation aerosol characterized by less than 10% drug degradation products by weight, and an MMAD of less than 5 microns.

11. (previously amended) The method according to Claim 10, wherein the condensation aerosol is formed at a rate greater than  $10^9$  particles per second.

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12. (previously amended) The method according to Claim 11, wherein the condensation aerosol is formed at a rate greater than  $10^{10}$  particles per second.

13.-18. (cancelled)

19. (previously presented) The condensation aerosol according to Claim 1, wherein the condensation aerosol is characterized by an MMAD of 0.1 to 5 microns.

20. (previously presented) The condensation aerosol according to Claim 1, wherein the condensation aerosol is characterized by an MMAD of less than 3 microns.

21. (currently amended) The condensation aerosol according to Claim 20 1, wherein the condensation aerosol is characterized by an MMAD of about 0.2 and to about 3 microns.

22. (previously presented) The condensation aerosol according to Claim 1, wherein the condensation aerosol is characterized by less than 5% drug degradation products by weight.

23. (previously presented) The condensation aerosol according to claim 22, wherein the condensation aerosol is characterized by less than 2.5% drug degradation products by weight.

24. (previously presented) The condensation aerosol according to Claim 1, wherein the solid support is a metal foil.

25. (previously presented) The condensation aerosol according to Claim 1, wherein the drug is dolasetron.

26. (previously presented) The condensation aerosol according to Claim 1, wherein the drug is granisetron.

27. (previously presented) The condensation aerosol according to Claim 1, wherein the drug is metoclopramide.

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28. (previously presented) The method according to Claim 10, wherein the condensation aerosol is characterized by an MMAD of 0.1 to 5 microns.
29. (previously presented) The method according to Claim 10, wherein the condensation aerosol is characterized by an MMAD of less than 3 microns.
30. (currently amended) The method according to Claim 29 10, wherein the condensation aerosol is characterized by an MMAD of about 0.2 to about 3 microns.
31. (previously presented) The method according to Claim 10, wherein the condensation aerosol is characterized by less than 5% drug degradation products by weight.
32. (previously presented) The method according to Claim 31, wherein the condensation aerosol is characterized by less than 2.5% drug degradation products by weight.
33. (previously presented) The method according to Claim 10, wherein the solid support is a metal foil.
34. (previously presented) The method according to Claim 10, wherein the drug is dolasetron.
35. (previously presented) The method according to Claim 10, wherein the drug is granisetron.
36. (previously presented) The method according to Claim 10, wherein the drug is metoclopramide.
37. (previously presented) A condensation aerosol for delivery of dolasetron, wherein the condensation aerosol is formed by heating a thin layer containing dolasetron, on a solid support, to produce a vapor of dolasetron, and condensing the vapor to form a condensation

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aerosol characterized by less than 5% dolasetron degradation products by weight, and an MMAD of about 0.2 to about 3 microns.

38. (previously presented) A condensation aerosol for delivery of granisetron, wherein the condensation aerosol is formed by heating a thin layer containing granisetron, on a solid support, to produce a vapor of granisetron, and condensing the vapor to form a condensation aerosol characterized by less than 5% granisetron degradation products by weight, and an MMAD of about 0.2 to about 3 microns.

39. (previously presented) A condensation aerosol for delivery of metoclopramide, wherein the condensation aerosol is formed by heating a thin layer containing metoclopramide, on a solid support, to produce a vapor of metoclopramide, and condensing the vapor to form a condensation aerosol characterized by less than 5% metoclopramide degradation products by weight, and an MMAD of about 0.2 to about 3 microns.

40. (previously presented) A method of producing dolasetron in an aerosol form comprising:

a. heating a thin layer containing dolasetron, on a solid support, to produce a vapor of dolasetron, and  
b. providing an air flow through the vapor to form a condensation aerosol characterized by less than 5% dolasetron degradation products by weight, and an MMAD of about 0.2 to about 3 microns.

41. (previously presented) A method of producing granisetron in an aerosol form comprising:

a. heating a thin layer containing granisetron, on a solid support, to produce a vapor of granisetron, and  
b. providing an air flow through the vapor to form a condensation aerosol characterized by less than 5% granisetron degradation products by weight, and an MMAD of about 0.2 to about 3 microns.

42. (previously presented) A method of producing metoclopramide in an aerosol form comprising:

- a. heating a thin layer containing metoclopramide, on a solid support, to produce a vapor of metoclopramide, and
- b. providing an air flow through the vapor to form a condensation aerosol characterized by less than 5% metoclopramide degradation products by weight, and an MMAD of about 0.2 to about 3 microns.

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REMARKS

A Notice of Allowance was mailed in the above-captioned application on October 18, 2005. The Notice of Allowance included an Examiner's amendment. On October 20, 2005 Applicant filed an Amendment under 37 C.F.R. § 1.312(a) requesting entry of the present amendments that have been made to claims 1 and 21 to correct minor typographical errors. However, the claims presented in that Amendment did not reflect the amendments made in the Examiner's amendment.

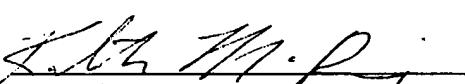
This Supplemental Amendment under 37 C.F.R. § 1.312(a) includes the amendments made in the Examiner's amendment, amendments made in the October 20, 2005 filing and additional amendments to claims 21 and 30 to correct dependency. The claims as presented herein reflect the claims as allowed by the Examiner and the amendments sought pursuant to 37 C.F.R. § 1.312(a).

The Examiner is encouraged to call and discuss this case with the undersigned should there be any questions regarding this amendment.

No fees are believed due with this amendment; however, the undersigned hereby authorizes the charge of any fees created by the filing of this document or any deficiency of fees submitted herewith to be charged to deposit account No. 19-5117.

Respectfully submitted,

Date: January 18, 2006

  
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January 18, 2006